

REMARKS

Claims 1-36 are present in this application and have been subjected to restriction by the Examiner under 35 U.S.C. §121 (37 C.F.R. §1.142) as follows:

Group I, Claims 1-2, 4-8, 25-29, 31 and 33-36, drawn to a transgenic plant, plant cell or protoplast or host cell comprising a nucleotide sequence for an SH2A or SH2A-like gene, and to a construct comprising a nucleotide sequence encoding an SH2A or SH2A-like protein, classified in class 536, subclass 23.6. For Invention I, restriction to a single nucleic acid sequence is also required under 35 U.S.C. §121. Therefore, if Invention I is elected, a single nucleic acid sequence must also be elected.

Group II, Claims 3 and 33-36, drawn to a transgenic plant comprising an SH2A or SH2A-like protein, classified in class 800, subclass 370.

Group III, Claim 9, drawn to a method for modulating growth or survival or cultured cells under hypoxic conditions by modulating the level or activity of an SH2A or SH2A-like protein, classified in class 435, subclass 471, for example.

Group IV, Claims 10-17, drawn to a method for modulating growth response in cultured cells and a method for modulating growth response in an organism by modulating the level or activity of an SH2A or SH2A-like protein, classified in class 435, subclass 455, for example.

Group V, Claim 18, drawn to a method for producing a plant which is adapted to growth in hypoxic conditions by transformation using a coding sequence for an SH2A or SH2A-like gene, classified in class 800, subclass 290, for example.

Group VI, Claim 19, drawn to a method for improving survival of a plant in conditions of low oxygen, classified in class 800, subclass 278, for example.

Group VII, Claim 20, drawn to a method for improving water logging tolerance in a plant by transformation using a

coding sequence for an SH2A or SH2A-like gene, classified in class 435, subclass 468, for example.

Group VIII, Claims 21-22, drawn to a method for inducing gibberellin biosynthesis in a plant or plant cell by transformation using a coding sequence for an SH2A or SH2A-like gene, classified in class 800, subclass 260, for example.

Group IX, Claims 23-24, drawn to a method of regulating an anaerobic response protein in a plant cell by transformation using a coding sequence for an SH2A or SH2A-like gene, classified in class 435, subclass 446, for example.

Group X, claim 30, drawn to a construct comprising an SH2A or SH2A-like gene promoter, classified in class 435, subclass 320.1, for example.

Group XI, Claim 32, drawn to an isolated SH2A-like protein, classified in class 530, subclass 370, for example. For Invention IX, restriction to a single amino acid sequence is also required under 35 U.S.C. §121. Therefore, if Invention IX is elected, a single amino acid sequence must also be elected.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents distinct inventions stating that the polynucleotide sequences of Invention I are unrelated to each other as are the polypeptide sequences of Invention XI. Citing MPEP §806.04, and MPEP §808.01, the Examiner has asserted that the different nucleotide and protein sequences encompassed by the invention, represent structurally different polynucleotide or structurally different polypeptides and that "where structural identity is required" the sequences have different effects.

With respect to the claims of Groups I-II, III-IX and X-XI, the Examiner's position is that the claims are unrelated since it can be shown that they are not disclosed as capable of use together, they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01).

The Examiner has also asserted that the claims of Groups I and V-IX are related as product and process of use. Citing MPEP §806.05 (h), the Examiner's position is that the claimed product may be used in a materially different process of using that product and that the claims therefor allegedly define different inventions.

Accordingly, it is the Examiner's position that each group of claims set forth above requires individual consideration as to patentability.

As indicated, and in order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 1-2, 4-8, 25-29, 31 and 33-36, and reserves the right to file one or more divisional applications directed to the non-elected subject matter in this application. Further, Applicant elects with traverse, cyclins, as the protein in these claims. Further, as requested by the Examiner, Applicants also provisionally elect SEQ ID NO:1 as the nucleic acid sequence encoded by the claims of Group I.

However, pursuant to 37 C.F. R. § 1.111 and § 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof for the following reasons.

An Examiner's authority to require restriction is defined and limited by statute:

If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. 121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without independent and distinctness, a restriction requirement is unauthorized.

In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement. Claim 32 (Group IX) is drawn to an isolated nucleic acid molecule encoding an SH2A-like protein. The claims of Group I, Claims 1-2, 4-8, 25-29, 31 and 33-36 are directed to a transgenic plant, plant cell, protoplast or host cell comprising a nucleotide sequence for an SH2A or SH2A-like gene and to a construct comprising same. Claims 3 and 33-36 (Group II) are directed to a product of the claims of Group I, i.e., plants comprising an SH2A or SH2A-like protein. Thus, the product Claims 3 and 33-36 cannot be considered "independent" of Claim 32 drawn to DNA encoding the SH2A or SH2A-like protein product and related embodiments (Claims 1-2, 4-8, 25-29, 31 and 33-36). Further, the Claims of Group III, V, VI, VII and IX all relate to methods of modulating growth or survival of cells and plants, including production of such plants under conditions of hypoxic (low oxygen) including such conditions of water logging. In all of these methods, the claims of Groups I, II and IX are involved since such modulating growth or survival is achieved using the nucleic acid sequences of Group IX to produce the transgenic plant cell, protoplasts, a host cell comprising a nucleotide sequence from a SH2A or SH2A-like gene. Claims 1-8, 25-29 and 31-36 are therefore very clearly interrelated and interdependent, not "independent and distinct."

The interdependence of the claimed SH2A and SH2A-like protein, the nucleotide sequence encoding the same, a plant, plant cell, protoplast, or host cell comprising said nucleotide sequences, as well as processes for obtaining improved growth and adaptation to hypoxic conditions, such as water logging is confirmed --indeed, it is mandated-- by virtue of the fact that the description requirements of 35 U.S.C. §112 compel disclosure of all aspects of the

invention in the one application which applicants have filed. An application claiming the SH2A or SH2A-like protein encoding sequences is required to disclose inter alia how to make that invention: in other words, a description of the means and method for producing the SH2A or SH2A-like protein is a mandatory part of the application to the plant-expressing SH2A or SH2A-like protein product. Likewise, a patent application claiming a nucleotide sequence encoding a SH2A or SH2A-like protein and a plant cell comprising said nucleotide sequence, as well as the method for making said plant is required to disclose inter alia, the product and use of such a product. Indeed, if any of these aspects of a complete disclosure were omitted --perhaps by an applicant relying on what the Patent and Trademark Office considers "independent and distinct"-- the application could be considered defective under §112, first paragraph.

Consequently, it is clear that aspects of a given invention, such as a product, its use, and the process of producing that product, are necessarily interdependent, not independent, from each other.

In addition, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973).

This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), Applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or a compromise of the term of their patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, *Studiengesellschaft Kohle mbH v. Northern Petrochemical Co.*, 784 F.2d 351, 355, 228, U.S.P.Q. 837, 840 (Fed. Cir. 1986). In *Gerber Garment Technology Inc. v. Lectra Systems Inc.*, 916 F.2d 683, 16 U.S.P.Q. 2d 436 (Fed. Cir. 1990), the Federal Circuit held that § 121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from

clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects of a unitary invention are claimed.

The Examiner has justified the restriction requirement in this case in a number of ways: recital of applicable section of the Manual of Patent Examining Procedure (M.P.E.P. §§806.04, 808.01; and 806.05(h) and references to the different classes and subclasses of the Patent and Trademark Office classification system in which the eleven groups of claims would allegedly be classed. Neither basis justifies the restriction requirement in this application.

The particular reason give by the Examiner to justify restriction between the different groups is that either (i) the different groups of claims have different modes of operation, different functions, and different effects or (ii) the process of using the product are claimed can be practical with another materially different product or (2) the product as claimed can be used in a materially different process of using that product such as a method of producing a recombinant protein.

The Examiner has then stated that since the "inventions" are distinct for this reason, they have acquired a separate status in the art due to their divergent subject matter as shown by their separate classification.

Reference to the Manual of Patent Examiner Procedure does not establish compliance with the narrow statutory authorization for restriction requirements. The Manual simply states the policy of the Patent and Trademark Office without force of law; it is not authority for expanding or altering a statutory grant of authority.

The PTO can prescribe requirements in the MPEP, providing those requirements are not inconsistent with the statute, the rules or the case law of the PTO's reviewing court.

In re Fressola, 22 U.S.P.Q.2d 1828, 1832 (Comm'r. PTO, 1992). The fact is, as demonstrated above, that inventions related as set forth in M.P.E.P. §§806.05(h), 806.04 and 808.01 are nonetheless not independent and distinct; therefore, the Manual is not proper authority for requiring restriction here.

Reliance on the supposed classification of the groups of claims does not establish independent and distinctness. The classification system has not statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims he assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patent assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Hence, it is again respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Alternatively, Applicants respectfully ask the Examiner to rejoin the claims of Groups I, II, III, IV, V, VI, VII, IX and XI.

Respectfully submitted,



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